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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,068	02/26/2002	Christopher H. Evans	018484-002121US	3205

7590 02/10/2006

JHK LAW
P.O. BOX
LA CANADA, CA 91012-1078

EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,068	EVANS ET AL.	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/06/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-157* is/are pending in the application.

4a) Of the above claim(s) *1-142* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *143-157* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 12/06/2005 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-157 are pending. Claims 1-142 remain withdrawn. The sections of 35 U.S.C. not included in this office action can be found in a previous office action. An action on the merits follows.

Claims 143-157 drawn to an adenovirus as the species of vector and IL-10 as the species of polynucleotide encoding a cytokine or biologically active fragment are currently under consideration.

Specification

Applicant's explanation as to which specification should be examined is appreciated. However, applicant has not their obligations under 37 CFR 1.125 because the filing of 8/12/2002 doesn't include a statement regarding new matter. See MPEP 608.01(g).

Claim Rejections - 35 USC § 112

The rejection of claims 143-157 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Response to Arguments

Applicant's arguments filed 12/06/2005 have been fully considered but they are not persuasive. Applicant argues that any biologically active fragment is enabled by the specification and the state of the art. Applicant is reminded that this rejection is separate from the enablement rejection under 35 U.S.C. 112, first paragraph. The operative issue is lack of written description, not lack of enablement. Applicant should note that the determination on whether the specification provides adequate written description, is made in view of the level of knowledge present in the art at applicant's earliest priority date, in this case 12/14/1993.

Further, applicant argues that a fragment of a gene or protein has a definite size and sequence and is limited by a finite number of molecular species. This is a truism and does not address any of the substantive issues raised in the previous office action.

Applicant is reminded that the first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written description of the invention." This requirement is separate and distinct from the enablement requirement. See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). The written description requirement has several policy objectives. "[T]he essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." In re Barker, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others

from practicing the invention for the duration of the patent's term. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003);< Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116.

Applicant has not indicated where in the specification they provide a description sufficient to fully describe, or demonstrate possession of the genus of nucleic acids encoding biologically active fragments of IL-10, which can inhibit any IL-1, induced responses in any mammal. Further, the art of record at the time of filing does not indicate that the structure of IL-10 was understood well enough to determine the functional domains that can inhibit an IL-1 induced responses in any mammal. Due to the lack of guidance in the specification on what constitutes a biologically active fragment of IL-10 and the lack of guidance in the art at the time of filing, a killed practitioner would be unable to determine that an applicant has invented the genus of subject matter which is claimed. Given applicant's lack of substantive arguments the basis of this rejection is maintained for the reasons stated above and in the prior office action of 6/06/2005.

The rejection of claims 143-157 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not provide an enabling disclosure for a method of inhibiting any IL-1 induced biological response in any mammal by administering, by any route, any polynucleotide encoding IL-10.

Response to Arguments

Applicant's arguments filed 12/06/2005 have been fully considered but they are not persuasive. Applicant argues that it would not require undue experimentation to determine what nucleotides would counter the negative effects of IL-1 and therefore any biological fragment having the indicated activity may be used. It is noted that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991). Applicant has not indicated where in the specification such guidance is to be found. Further, applicant argues that any biologically active fragment of IL-10 is fully enabled by the specification and the state of the art. However, it is noted that applicant has not indicated where in the specification, or in the prior art of record, the basis of such enablement is to be found. The determination on whether the specification provides sufficient guidance to enable the claimed invention is made in view of the level of knowledge present in the art at applicant's earliest priority date, in this case 12/14/1993. While it was known at the time of filing that IL-10 could generally inhibit cytokine synthesis by human monocytes, including Il-1α and IL-1β among others, it was not known what specific domains of IL-10 were responsible for this inhibition (de Waal et al. (1991) J. Exp. Med. 174:1209-1220; Abstract}.

Finally, applicant argues that the examples section fully supports the claimed invention for use in gene therapy. However, applicant has not addressed any of the issues raised in the prior office action in regards to the art taught unpredictability. Further, none of the working examples disclose any results from experiments actually performed. Specifically, applicant does not address the failure of the specification to provide any guidance on any regulatory elements to be operably linked to the IL-10 sequence, such as a promoter, kozak sequence, or poly A site. Further the specification does not specify whether the IL-10 polynucleotide sequence is to be constitutively expressed or under the control of an inducible promoter. Finally, the specification does not provide any information on the routes of administration of the IL-10 nucleic acid. In the related field of DNA based vaccines, the route of delivery is known to have a significant effect on the efficiency of expression. As was previously stated: Verma et al. states that, the Achilles heel of gene therapy is gene delivery, and that, most of the approaches suffer from poor efficiency of delivery and transient expression of the gene. Applicant has not provided any evidence that the specification as filed, or the art of record in 1993, provided sufficient guidance to enable a practitioner to reliably predict how to practice the invention as claimed. Finally, applicant has not indicated where in the specification there is guidance that "fully supports administering the polynucleotide into the site of interest in a mammal." (Reply of 12/06/05). Applicant's response to these points is a broad unsupported generalization arguing that the claims are enabled for gene therapy. This is not considered to be persuasive. Given applicant's lack of substantive arguments the basis of this rejection is maintained for the reasons stated above and in the prior office action of 6/06/2005.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
Patent Examiner
Art Unit 1632

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630